UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION **Relates to: ALL CASES**	**MDL No. 13-md-2452-AJB-MDD** **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO COMPEL AGAINST ALL DEFENDANTS FOR THEIR COMMUNICATIONS WITH OR RELATED TO CERTAIN FOREIGN REGULATORY AGENCIES**

Introduction

Several foreign regulatory agencies, including those in Canada, Switzerland, Israel, and Japan, have investigated whether Defendants' incretin drugs can cause pancreatic cancer, and have requested from Defendants scientific information relating to that question. Plaintiffs seek those particular communications ("Foreign Regulatory Files"), as well as pertinent internal company communications related to the Foreign Regulatory Files. Despite the obvious relevance to general causation, Defendants have refused to even search, much less produce, the Foreign Regulatory Files; Plaintiffs learned of this highly probative evidence via sporadic references to the inquires in Defendants' custodial files.[1]

The documents are also relevant to impossibility preemption, because any scientific evidence provided to foreign regulatory officials but *not* to the FDA could show under-reporting or misreporting by Defendants to the FDA, evidence which this Court

[1] It is likely that regulatory agencies in other countries have also raised the general causation issue with Defendants, and Plaintiffs are scouring the custodial files for references, but Defendants are in a far better position to know which regulatory authorities have asked these questions, and to which regulatory authorities they have provided information.

recognized "Plaintiffs must have a full opportunity to discover..." (Doc. 572 at 5). Defendants cannot deny that the Foreign Regulatory Files contain information *not* provided to FDA; part of their objection to producing the Foreign Regulatory Files is that de-duplication of the Foreign Regulatory Files to cull out documents already submitted to FDA would impose an undue burden on them, and that it would be easier for them simply to produce the Foreign Regulatory Files *in toto*. Plaintiffs do not oppose this solution, but Defendants refuse either.

A. A Brief Summary of Meet and Confer Efforts

On August 20, 2014, counsel for the parties participated in a conference call regarding Defendants' objections to producing foreign regulatory information and documents related to the incretin drugs. Plaintiffs took the position that they take in this motion. Defendants agreed to consider production of the Foreign Regulatory Files regarding Canada and other foreign regulators, if any, that had inquired of them regarding the relationship between their incretin drugs and pancreatic cancer. However, Defendants ultimately refused to produce any of the requested information other than foreign regulatory documents incidentally produced with custodial files (and, for Merck, site files).[2]

To limit the burden on Defendants, Plaintiffs proposed that the foreign discovery exclude documents already submitted to the FDA. The Court suggested this possible compromise in its Order Setting Discovery Protocol Dispute. (Doc. 568.) Defendants rejected this proposal; they say it would be quicker and less expensive for them to

[2] Curiously, Defendants have taken the position that Foreign Regulatory Files are not relevant to general causation and/or preemption, except for the EMA, which they relied upon during Science Days and in their preemption briefing to date. However, the only logical difference between the EMA and other Foreign Regulatory Files appears to be that Defendants believe that the EMA may support some of their arguments in this MDL and that other Foreign Regulatory Files may counter some of their arguments in this MDL.

produce the entire Foreign Regulatory Files rather than just those portions that have not already been produced elsewhere.

To limit the burden on Defendants, Plaintiffs proposed narrowing their request, as described in the next paragraph. Defendants rejected this proposal as well.

B-C. A Description of the Discovery Sought to be Compelled

Plaintiffs seek to compel the written communications relating to pancreatic cancer sent to or received from the foreign regulatory agencies of Canada, Switzerland, Israel, Japan, and France, any foreign regulatory agencies that have communicated with a Defendant about the relationship between incretins and pancreatic cancer, and internal company communications regarding those same communications. The specific interrogatories and requests to produce and objections are attached as Exhibit A.[3] As noted above, Defendants have refused to identify with which foreign regulatory agencies they have discussed pancreatic cancer. Plaintiffs provide a brief description of the probable cause for each agency, as discovered within custodial productions as follows:

Canada: Health Canada is the regulatory agency charged with the regulation of prescription drugs in Canada. [redacted]

Switzerland: SwissMedic is the regulatory agency charged with the regulation of prescription drugs in Switzerland. [redacted]

[3] Plaintiffs served General Causation Requests to Produce Nos. 25 and 51and Interrogatory No. 27 on all Defendants. Those interrogatories and requests encompass Foreign Regulatory Files and related internal company communications. The select interrogatories and requests to produce and Defendants' objections are attached as Exhibit A.

[redacted]

Israel: The Ministry of Health ("MOH") is the regulatory agency charged with the regulation of prescription drugs in Israel. [redacted]

Japan: The Pharmaceuticals and Medical Devices Agency ("PMDA") is the regulatory agency charged with the regulation of prescription drugs in Japan. [redacted]

[redacted]

[redacted] Additionally, when Merck provided FDA with a white paper concerning the relationship between Merck's incretin drugs and pancreatic cancer, "[s]tudies conducted only in Japan were excluded from all analyses." (Ex. F, MRKJAN 10000484683-703, at 690.) This is direct evidence that PMDA was concerned about whether incretin drugs can cause pancreatic cancer.

France: The French Healthcare Authority ("FHA") is the regulatory agency charged with the regulation of prescription drugs in France. [redacted]

D. Statement as to Why the Documents are Relevant and Necessary

The Foreign Regulatory Files as defined herein, and related internal company communications, are relevant to general causation because they contain documents concerning whether the incretin drugs are capable of causing pancreatic cancer. Plaintiff's requests are limited to foreign regulatory discovery regarding agencies that have communicated with a Defendant about whether incretin drugs can cause pancreatic cancer. Plaintiffs are not seeking to compel production of all files concerning foreign regulation of incretin drugs. Therefore, Defendants contention that discovery sought to be compelled does not contain evidence relevant to general causation does not make sense.

The Foreign Regulatory Files are also relevant to impossibility preemption. Indeed, the Defendants themselves made the files relevant to this issue by asserting as an affirmative defense that FDA would not have permitted Defendants to change the incretin drug labels in any way with respect to pancreatic cancer. To establish their affirmative defense of impossibility preemption, Defendants have the burden to show with clear evidence that FDA would not have permitted a change in incretin drug labeling. Plaintiffs are entitled to challenge that assertion with instances of under-reporting or misreporting to the FDA. As day follows night, Defendants will say *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), bars Plaintiffs from challenging the affirmative defense of impossibility preemption with such evidence. However, *Buckman*-style "fraud on the FDA" preemption has no application here, where Plaintiffs assert "a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*." *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (*cert. denied*, -- U.S. --, 134 S.Ct. 2839 (2014)). *Buckman* is not at all germane to the issue before the Court; it is a red herring.[4]

[4] The inapplicability of *Buckman* is explained at length in Plaintiffs' reply memorandum in support of a separate motion to compel and will not be reiterated at length here. The discussion appears in Document 613 at pages 5-6.

Defendants' claim that the discovery is unduly burdensome is also without merit. To the extent providing the discovery will impose a burden (which is very different from an undue burden) on Defendants, that burden is a result of their assertion of impossibility preemption and of the reality that the Foreign Regulatory Files contain information relevant to general causation that Plaintiffs cannot obtain from any source other than Defendants.

Conclusion

For the foregoing reasons, Plaintiffs respectfully request the Court enter an Order compelling Defendants to produce the written communications sent to or received from the foreign regulatory agencies of Canada, Japan, Switzerland, Israel, and France; compelling Defendants to produce the written communications sent to or received from other foreign regulatory agencies, if any, that have communicated with a Defendant about the relationship between incretins and pancreatic cancer; compelling Defendants to produced internal company communications regarding same; and granting such further or other relief as is proper.

DATED: September 12, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2014, I caused the above document to be filed via the CM/ECF system for the Southern District of California, and the CM/ECF system served the same upon all registered users at their registered email addresses.

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I hereby certify that on October 7, 2014, I caused the above redacted document to be filed via the CM/ECF system for the Southern District of California, and the CM/ECF system served the same upon all registered users at their registered email addresses.

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